IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF MISSOURI
EASTERN DIVISION

UNITED STATES OF AMERICA, *ex rel.*, Donna Chronister Plaintiff, v. PROGRESSIVE PAIN MANAGEMENT, P.C., DR. NEHAL P. MODH, M.D., US LABORATORY, and JEANNINE YEAST. Defendants.	)	Civil Action No. JURY TRIAL DEMANDED

VERIFIED COMPLAINT

Plaintiff, brought on behalf of the United States of America by Donna Chronister ("Relator"), for its Complaint against Defendants Progressive Pain Management ("PPM"), Dr. Nehal P. Modh ("Dr. Modh"), US Laboratory ("USL"), and Jeannine Yeast ("Yeast") hereby states as follows:

INTRODUCTION

This is a civil qui tam action brought on behalf of the United States of America by Relator against PPM, Nehal P. Modh, USL and Jeannine Yeast, subject to the qui tam provisions of the Civil False Claims Act and pursuant to 31 U.S.C. §§ 3729-33. This action is also brought pursuant to the provisions of the Federal Anti-Kickback Statute, 42 U.S.C. § 1320a-7.

1. Defendant PPM is a facility that specializes in palliative care and provides outpatient services, such as anti-inflammatory joint injections and office visits.

2. Nehal P. Modh, M.D. is a physician specializing in interventional pain management and is the principal physician at PPM. Dr. Modh is responsible for prescriptions of drugs for pain management, including opioids.

3. Jeannine Yeast is the office manager of PPM and an employee of USL, working remotely for USL from the PPM office and sending urine samples to USL.

4. USL is a laboratory in California that processes patient body tissues and samples sent from PPM.

5. USL compensated Yeast to induce her to arrange for USL's facility to receive urine samples from PPM patients for drug testing services covered by federal healthcare programs, in violation of the 42 U.S.C. 1320a-7(b)(2).

6. PPM, Dr. Modh, and Yeast submit claims for outpatient pain management services to Government healthcare payors.

7. PPM falsified CMS-1500 claims forms for these services by billing for ultrasound-guided injections when ultrasound machines were never used for these injections.

8. PPM falsified CMS-1500 claims forms for injection services that were medically unnecessary, in violation of Medicare Part B regulations, by falsely certifying that the services were medically necessary.

9. PPM falsified CMS-1500 claims forms by billing under Dr. Modh for patient exams when a Nurse Practitioner ("NP"), Ashley Davis, had actually provided these services without direct supervision by a physician.

10. PPM falsified CMS-1500 claims forms by billing for exams that were more comprehensive than those that were actually performed.

11. Defendants PPM, Dr. Modh, and Yeast then submitted these false and fraudulent CMS-1500 claims forms to MO HealthNet, the Medicare Administrative Contractor ("MAC") for Missouri, and Medicare Advantage Plan Providers ("MAPs").

12. Based on these false records, the MAC and MAPs paid PPM, Dr. Modh, and Yeast for pain management services with money received from Medicare. MO Healthnet also paid PPM, Dr. Modh, and Yeast for pain management services with Medicaid funds.

13. Defendant Yeast fraudulently signed prescriptions for opioid medications when Defendant Dr. Modh was not in the office.

14. These fraudulently signed prescriptions were then submitted by Defendants to pharmacies and patients, who then presented claims based on these forged prescription signatures to Medicare Part D providers and Medicaid.

15. Based on these false records, Medicare and Medicaid provided reimbursements for these medications.

THE PARTIES

16. Relator brings this action on behalf of the United States of America against PPM, Dr. Nehal P. Modh, M.D., US Laboratory, and Jeannine Yeast for treble damages and civil penalties arising from PPM's, Dr. Modh's, USL's, and Yeast's false statements and false claims in violation of the Civil False Claims Act, 31 U.S.C. §§ 3729 *et seq.* The violations arise out of false billing and patient record practices, paid by Medicare, Medicaid, Tricare, and other Government Payors for services provided by PPM, Dr. Modh, USL, and Yeast. The violations also arise out of improper compensation arrangements, in violation of 42 U.S.C. § 1320a-7(b)(2), between USL and Yeast that resulted in referrals for urine testing services covered by federal healthcare programs from PPM to USL and in double billing of these programs.

17. As required by the False Claims Act, 31 U.S.C. § 3730(b)(2), Relator has provided to the Attorney General of the United States and to the United States Attorney for the Eastern District of Missouri a statement of all material evidence and information related to the complaint. This disclosure statement is supported by material evidence known to Relator at the time of filing, establishing the existence of PPM's, Dr. Modh's, USL's, and Yeast's false claims. Because the statement includes attorney-client communications and work product of Relator's attorneys, and is submitted to the Attorney General and the United States Attorney in their capacity as potential co-counsel in the litigation, Relator understands this disclosure to be confidential.

18. Relator is a citizen of the United States and resident of the State of Missouri.

19. Relator brings this action based on her direct, independent, and personal knowledge and also, on information and belief.

20. Relator is an original source of this information to the United States. She has direct and independent knowledge of the information on which the allegations are based and has voluntarily provided the information to the government included in this action under the False Claims Act, which is based on this information.

21. Relator was an employee of PPM from May 2013 to September 2018. At the time of her departure, Relator was a receptionist.

22. In this position, Relator would advise PPM, Dr. Modh, Yeast, and USL with respect to matters involving the personnel, operations, compliance, and financial aspects of these companies.

23. Relator left her employment in September 2018 because she was uncomfortable with the fraudulent and unethical billing practices done by Defendants.

24. Defendant PPM provides treatments, including, but not limited to, injections for peripheral nerves, trigger points, and sacroiliac and spinal joints; epidural injections in the lumbar, thoracic and cervical regions; transforaminal injections; and claims to provide ultrasonically-guided injections, for chronic pain resulting from injury or illness. PPM is located at 1145 E Gannon Dr., Festus, MO 63028.

25. Defendant Dr. Nehal P. Modh, M.D. is a doctor specializing in interventional pain management who is the principal physician at Defendant PPM's office. Dr. Modh is responsible for prescribing pain medications, including opioids.

26. Defendant Jeannine Yeast is the office manager for Defendant PPM, and she does not possess any kind of medical or healthcare degree or certification.

27. Defendant USL provides urine drug testing services for PPM and is located at 3194-A Airport Loop Drive, Costa Mesa, CA 92626.

28. Defendant Jeannine Yeast was/is compensated by USL in exchange for urine samples, and sends patients' urine samples to USL from PPM's office by mail.

JURISDICTION AND VENUE

29. This action arises under the False Claims Act, 31 U.S.C. § 3729. This Court has subject matter jurisdiction over this case pursuant to 31 U.S.C. §§ 3732(a) and 3730(b). This Court also has jurisdiction pursuant to 28 U.S.C. §§ 1345 and 1331.

30. This action also arises under the Federal Anti-Kickback Statute, 42 U.S.C § 1320a-7(b)(1) and (2). This court has subject matter jurisdiction over this case pursuant to 28 U.S.C. § 1331.

31. This court has personal jurisdiction over PPM because it's principal place of business is in the Eastern District of Missouri and PPM transacts business in the Eastern District of Missouri.

32. This court has personal jurisdiction over Dr. Modh and Jeannine Yeast because they are residents of the Eastern District of Missouri and transact business here.

33. This court has personal jurisdiction over Defendant USL because it has purposefully availed itself of the State of Missouri in hiring and retaining an employee, providing compensation to a Missouri resident, and soliciting business from PPM and Defendant Jeannine Yeast, who works remotely for USL and sends urine samples from Missouri patients for processing to USL.

34. Venue is proper in this District pursuant to 31 U.S.C. § 3732(a), because the acts proscribed by 31 U.S.C. § 3729 *et seq.* and 42 U.S.C. § 1320a-7(b)(1) and (2) and complained of herein took place in this District, and is also proper pursuant to 28 U.S.C. § 1391(b) and (c), because at all times material and relevant, Defendants transact and transacted business in this District and Defendants Dr. Modh and Yeast are residents of this District.

THE FALSE CLAIMS ACT

35. The False Claims Act ("FCA") provides, in pertinent part:

(a) Any person who (A) knowingly presents, or causes to be presented, a false claim for payment or approval; (B) knowingly makes, uses, or causes to made or used, a false record or statement material to a false or fraudulent claim, is liable to the United States Government for a civil penalty of not less than $5,000 and not more than $10,000, plus 3 times the amount of damages which the Government sustains because of the act of that person.

(b) For purposes of this section, the terms "knowing" and "knowingly" mean that a person, with respect to information (1) has actual knowledge of the information; (2) acts in deliberate ignorance of the truth or falsity of the information; or (3) acts in reckless disregard of the truth or falsity of the information, and no proof of specific intent to defraud is required.

36. For the purposes of the FCA, "person," includes corporations. *Cook County, Ill. v. United States ex rel. Chandler*, 538 U.S. 119, 125 (2003).

37. There are four elements that must be met to succeed in a qui tam action under § 3729(a)(1)(A): (1) a false statement or fraudulent course of conduct; (2) that was made or carried out with the requisite scienter; (3) that was material; and (4) that caused the government to pay out money. *U.S. ex rel. Johnson v. Kaner Medical Group, P.A.*, 641 Fed. Appx. 391, 394 (5th Cir. 2016).

38. "Material" means "having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property." 42 U.S.C. § 3729(b)(4).

39. Factual falsity is established when the claim involves an incorrect description of goods or services provided or a request for reimbursement for goods or services never provided. *U.S. v. Sci. Applications Int'l Corp.*, 626 F.3d 1257, 1266 (D.C. Cir. 2010).

40. A claim may be false if it falsely certifies compliance with an applicable statute, regulation or contract, and false certifications can be either express or implied. *U.S. v. Dynamic Visions, Inc.*, 216 F. Supp.3d 1, 14 (D.D.C. 2016).

41. A claim is false or fraudulent on the basis of implied certification when noncompliance with regulations is material to the Government's decision to reimburse the claims. See *Universal Health Servs., Inc., v. U.S.*, 136 S.Ct. 1989, 1996 (2016).

THE FEDERAL ANTI-KICKBACK STATUTE

42. The Federal Anti-Kickback Statue makes it a crime to knowingly and willfully offer, pay, solicit, or receive any remuneration to induce a person to (1) refer an individual to a person for the furnishing of any item or service covered under a federal healthcare program; or (2) purchase, lease, order, arrange for or recommend any good, facility, service, or item covered under a federal healthcare program. 42 U.S.C §§1320a-7(b)(1) and (2).

43. The term "any remuneration" encompasses any kickback, bribe, or rebate, direct or indirect, overt or covert, cash or in kind. 42 U.S.C. §§ 1320a-7b(b)(1). The Anti-Kickback Statute has been interpreted to cover any arrangement where one purpose of the remuneration was to obtain money for the referral of services or to induce further referrals. *U.S. ex rel. Westmoreland v. Amgen, Inc.*, 812 F. Supp.2d 39, 47 (D. Ma. 2011)(citing *United States v. Kats*, 871 F.2d 105, 108 (9th Cir. 1989); *United States v. Greber*, 760 F.2d 68, 69 (3d Cir. 1985)).

44. Any person (including an organization, agency, or other entity) that knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim for payment for items and services furnished under a Federal healthcare program shall be subject to civil monetary penalties of $100,000 for each false record or statement. 42 U.S.C.A. § 1320a(8). In addition, such persons shall be subject to an assessment of not more than 3 times the total amount claimed for each item or service in lieu of damages sustained by the United States or a State agency because of such claim. *Id.*

FACTS COMMON TO ALL COUNTS

A. Medicare

45. The Medicare program was created in 1965 as part of the Social Security Act, 42 U.S.C. § 1395 *et seq*. Medicare is a federal health insurance program for the elderly and people

with disabilities. *U.S. ex rel. Groat v. Boston Heart Diagnostics*, 255 F. Supp.3d 13, 17 (D.D.C. 2017).

46. During the relevant time period, the United States administered and funded Medicare, pursuant to the Social Security Act, 42 U.S.C. § 1395 *et seq.* By becoming a participating provider in Medicare, enrolled providers agree to abide by the rules, regulations, policies and procedures governing claims for payment, and to keep and allow access to records and information as required by Medicare. In order to receive Medicare funds, enrolled providers, together with authorized agents, employees, and contractors, are required to abide by all provisions of the Social Security Act, the regulations promulgated under the Act, and all applicable policies and procedures issued by the State.

47. The Centers for Medicare and Medicaid Services ("CMS") is an agency of the United States Department of Health and Human Services ("HHS") and is responsible for the administration of the Medicare Program.

48. Medicare consists of two basic parts: Part A (42 U.S.C. §§ 1395c-13951-5) and Part B (42 U.S.C. §§ 1395J-1395w-4). Medicare Part A covers a variety of inpatient services. Medicare Part B covers medically necessary services for diagnosis and treatment, including outpatient care.

49. Medicare Administrative Contractors ("MACs") are private healthcare insurers that have been awarded a contract by CMS to process Medicare Part A and Part B (A/B) medical claims in a specified geographic jurisdiction.

50. Medicare Advantage Plans are offered by private companies that contract with Medicare and these types of plans fall under Medicare Part C. These plans cover all Part A and

Part B benefits. Medicare Advantage Plans include: Health Maintenance Organizations ("HMOs"), Preferred Provider Organizations ("PPOs"), and Private Fee-for-Service Plans.

i. Medicare Part B – Outpatient Services

51. The Medicare Part B Physicians Fee Schedule establishes the reimbursement rate for services performed by medical professionals. The reimbursement values for services under the fee schedule are calculated by multiplying (1) the relative value of a service; (2) the conversion factor for the particular year, and (3) the geographic adjustment factor applicable to the locality in which the service was provided. 42 U.S.C.A. § 1395w-4(b).

a. Outpatient Office Visits

52. Medicare Part B covers outpatient exams, such as those provided by Defendants, and medically necessary services during these visits, such as injections of anti-inflammatory medications provided by Defendants.

53. An entity seeking reimbursement for services provided to Medicare patients must submit a CMS-1500 form to the Medicare contractor. *U.S. ex rel. Groat*, 255 F. Supp.3d at 17. The CMS-1500 form reflects the treatment or services provided and identifies the entity that provided them. *Id.* at 18.

54. In order for outpatient services providers to be reimbursed by Medicare for Part B services, they must submit a CMS-1500 form with, among other things, an appropriate CPT code.

55. Outpatient office visits have varying comprehensiveness and are therefore coded at 5 levels depending on the thoroughness of the exam/services the patient received. The codes are 99211, 99212, 99213, 99214, and 99215, with 99211 being the least thorough exam and 99215 being the most comprehensive.

56. For outpatient office visits, CPT code 99213 is used to bill for exams where at least two of three components are present in the medical record: (1) An expanded problem focused history; (2) An expanded problem focused examination; and (3) Medical decision making of *low* complexity. Palmetto GBA, Palmetto GBA Video Script for Part B Established Patient Office Visits (CPT Codes 99211-99215), https://www.palmettogba.com/Palmetto/Providers.Nsf/files/Video_Part_B_CPT-Codes-for-Evaluation-and-Management-Office-Visits-Established.pdf/$File/Video_Part_B_CPT-Codes-for-Evaluation-and-Management-Office-Visits-Established.pdf (last visited July 18, 2019)(emphasis added).

57. For outpatient office visits, CPT code 99214 is used to bill for exams where at least two of three components are present in the medical record: (1) A *detailed* history; (2) A *detailed* examination; and (3) Medical decision making of *moderate* complexity (Emphasis added). *Id.*

b. Outpatient Injections

58. Injections into the joints, using steroids and other anti-inflammatory medications, are done for patients with chronic conditions, such as arthritis. Ultrasound machines may be used for guidance in injections involving joints that are difficult to inject.

59. In general, according to Dr. Roy Altman, M.D., professor of medicine and rheumatology at UCLA Medical Center in Los Angeles, patients should not have corticosteroid injections into any given joint more than once every three to four months. Jim Morelli, *Use of Corticosteroids in Osteoarthritis*, Arthritis Foundation, https://www.arthritis.org/living-with-arthritis/treatments/medication/drug-types/corticosteroids/corticosteroid-injections.php (last visited July 18, 2019). More frequent injections are not recommended because of the increased

risk of weakening tissues in the treated area. *Steroid Injections: Procedure Details*, Cleveland Clinic, https://my.clevelandclinic.org/health/treatments/4934-steroid-injections/procedure-details (last visited Jul. 17, 2019).

60. Ultrasound-guided injections are billed using 76942. CPT code 20611 indicates ultrasound-guided injections of a major joint or bursa (shoulder, hip, knee, subacromial bursa). CPT code 20610 indicates injection of major joint or bursa without ultrasound. Ultrasound-guided injections are reimbursed at a higher rate than unguided injections.

61. For instance, in 2018, 20610 had a non-facility price of $60.95, $61.95, or $57.89, depending on locality, and a facility price of $47.49, $47.64, or $45.78 under the Medicare Part B physician fee schedule. By comparison, in 2018, 20611 had a non-facility price of $91.20, $91.50, or $86.28, depending on locality, and facility price of $62.89, $63.07, or $60.81 depending on the Missouri locality. Physician Fee Schedule Search, CMS, http://www.CMS.gov/apps/physician-fee-schedule/search/search-criteria.aspx; (select year 2018, type of information: pricing information, select HCPCS criteria: list of HCPCS codes, select MAC Option: Specific MAC, enter HCPCS Code 20610 and 20611, select all modifiers, and select MAC: 05302 MISSOURI)

62. In 2017, 20611 had a non-facility price of $91.12, $91.23, or $85.91 and a facility price of $62.96, $63.04, or $60.72, depending on the locality in which these services were performed, while 20610 had a non-facility price of $60.95, $61.16, or $57.89 and a facility price of $47.49, $47.64, or $45.78, depending on the locality in which these services were administered, under the Part B fee schedule. Physician Fee Schedule Search, CMS, http://www.CMS.gov/apps/physician-fee-schedule/search/search-criteria.aspx; (select year 2017, type of information: pricing information, select HCPCS criteria: list of HCPCS codes, select

MAC Option: Specific MAC, enter HCPCS Code 20610 and 20611, select all modifiers, and select MAC: 05302 MISSOURI).

63. Medicare reimbursement for injection services requires use of the proper CPT code and certification that the injections are medically necessary. The CMS-1500 form requires the entity to certify that, among other things, the services on the form were medically necessary. *U.S. ex rel. Groat*, 255 F. Supp.3d at 18.

ii. Medicare Part B – Reimbursement of Nurse Practitioners

64. Medicare Part B also pays for services and supplies "incident to" the service of a physician and these services and supplies must be furnished under the direct supervision of the physician. 42 C.F.R. § 410.26.

65. "Direct supervision" means the level of supervision by the physician of auxiliary personnel as defined in 42 C.F.R. § 410.32(b)(3)(ii). 42 C.F.R. § 410.26(a)(2).

66. Direct supervision in the office setting means the physician must be present in the office suite and immediately available to furnish assistance and direction throughout the performance of the procedure. It does not mean that the physician must be present in the room when the procedure is performed. 42 C.F.R. § 410.32(b)(3)(ii).

67. CMS-1500 forms have a statement on the back which reads "for services to be considered 'incident to' a physician's professional services, 1) they must be rendered under the physician's direct supervision by his/her employee, 2) they must be an integral, although incidental part of a covered physician service, 3) they must be of kinds commonly furnished in physician's offices, and 4) the services of non-physicians must be included on the physician's bills."

68. When nurse practitioner services are billed as "incident to the service of a physician," the physician's Unique Provider Identification Number ("UPIN") is used on the bill submitted through the Medicare contractor. *U.S. v. R&F Properties of Lake County, Inc.*, 433 F.3d 1349, 1353 (11th Cir. 2005).

69. A provider may bill Medicare for nurse practitioner services under the nurse practitioner's own UPIN, indicating that the nurse practitioner has performed the service under some level of supervision by a physician, but the requirements of 42 C.F.R. § 410.26 have not necessarily been met. *Id.*

70. When billing using the nurse practitioner's UPIN, for services furnished beginning January 1, 1998, allowed amounts for the services of a nurse practitioner may not exceed 85 percent of the physician fee schedule amount for the service. 42 C.F.R. § 414.56(c).

iii. Medicare Part B – Medical Necessity and Laboratory Services

71. Medicare reimbursement requires that services provided be medically necessary. The CMS-1500 form requires the entity to certify that, among other things, the services on the form were medically necessary. *U.S. ex rel. Groat*, 255 F. Supp.3d at 18.

72. Medicare Part B pays for covered diagnostic laboratory tests that are furnished by the office of the patient's attending or consulting physician if that physician is a doctor of medicine or osteopathy. 42 C.F.R. § 410.32(d)(iii).

73. All diagnostic laboratory tests and other diagnostic tests must be ordered by the physician who is treating the beneficiary, that is, the physician who furnishes a consultation or treats a beneficiary for a specific medical problem and who uses the results in the management of the beneficiary's specific medical problem and tests not ordered by the physician who is treating the beneficiary are not reasonable and necessary. 42 C.F.R. § 410.32(a).

74. Nonphysician practitioners (that is, clinical nurse specialists, clinical psychologists, clinical social workers, nurse-midwives, nurse practitioners, and physician assistants) who furnish services that would be physician services if furnished by a physician, and who are operating within the scope of their authority under State law and within the scope of their Medicare statutory benefit, may be treated the same as physicians treating beneficiaries. 42 C.F.R. § 410.32(a)(2).

75. The physician or qualified practitioner who orders the service must maintain documentation of medical necessity in the beneficiary's medical record. 42 C.F.R. § 410.32(d)(2)(i).

76. The entity submitting the claim must maintain (A) the documentation it receives from the ordering physician or nonphysician practitioner and (B) the documentation that the information it submitted with the claim accurately reflects the information it received from the ordering physician or nonphysician practitioner. 42 C.F.R. § 410.32(d)(2)(ii).

iv. Medicare Part D

77. Medicare Part D provides prescription drug coverage to eligible individuals who are enrolled under Part B. 42 U.S.C.A. § 1305w-101(a). Unlike Parts A and B, Medicare Part D is based on a private market model, wherein Medicare contracts with private entities, known as Part D "sponsors" to administer prescription drug plans. *In re Plavix Marketing, Sales Practices and Products Liability Litigation*, 123 F. Supp.3d 584, 602 (D.N.J. 2015).

78. There are two main ways to get prescription drug coverage under Medicare Part D: (1) through a Medicare Prescription Drug Plan ("PDP"), which adds drug coverage to original Medicare; or (2) through a Medicare Advantage Plan ("MAP"), like an HMO or PPO, that offers Medicare prescription drug coverage.

79. Part D sponsors subcontract with pharmaceutical entities to provide drugs to beneficiaries. As a condition for payment from CMS, the sponsor agrees that its chief executive officer (CEO), chief financial officer (CFO), or an individual delegated the authority to sign on behalf of one of these officers, and who reports directly to the officer, must request payment under the contract on a document that certifies (based on best knowledge, information, and belief) the accuracy, completeness, and truthfulness of all data related to payment. The data may include specified enrollment information, claims data, bid submission data, and other data that CMS specifies. 42 CFR § 423.505(k)(1).

80. A Part D covered outpatient drug must be a drug that may be dispensed only upon prescription. 42 U.S.C.A. § 1396r-8(k)(2)(A).

B. Medicaid

81. Title XVIII of the Social Security Act, 42 U.S.C. § 1396, *et seq*. establishes Medicaid, a federally assisted grant program for the States. Medicaid enables the States to provide medical assistance and related services to needy individuals. CMS administers Medicaid on the federal level. Within broad federal rules, each state decides who is eligible for Medicaid, the services covered, payment levels for services, and administrative and operational procedures.

82. During the relevant time period, the United States provided funds to the California and Missouri Medical Assistance Program (Medicaid) under Title XIX of the Social Security Act, 42 U.S.C. § 1396 *et seq*. Enrolled providers of medical services to Medicaid recipients are eligible for payment for covered medical services under the provisions of Title XIX of the 1965 Amendments to the Federal Social Security Act. By becoming a participating provider in Medicaid, enrolled providers agree to abide by the rules, regulations, policies and procedures governing claims for payment, and to keep and allow access to records and

information as required by Medicaid. In order to receive Medicaid funds, enrolled providers, together with authorized agents, employees, and contractors, are required to abide by all provisions of the Social Security Act, the regulations promulgated under the Act, and all applicable policies and procedures issued by the State.

83. MO HealthNet is responsible in Missouri for the administration of services provided in accordance with Title XIX, Public Law 89-97, 1965 amendments to the federal Social Security Act, 42 U.S.C. § 301. MO HealthNet Division, http://dss.mo.gov/mhd/ (last visited July 18, 2019).

84. MO HealthNet payments shall be made on behalf of eligible needy persons who are unable to provide it in whole or in part, with any payments to be made on the basis of the reasonable cost of the care or reasonable charge for the services as defined and determined by the MO HealthNet division for the following services: (1) Laboratory and X-ray services; (2) Physicians' services, whether furnished in the office, home, hospital, nursing home, or elsewhere; (3) Drugs and medicines when prescribed by a licensed physician, dentist, podiatrist, or an advanced practice registered nurse; (4) Outpatient surgical procedures, including presurgical diagnostic services performed in ambulatory surgical facilities which are licensed by the department of health and senior services of the state of Missouri unless the beneficiary is eligible for Medicare Part B; and (5) The services of an advanced practice registered nurse with a collaborative practice agreement to the extent that such services are provided in accordance with chapters 334 and 335, and regulations promulgated thereunder. V.A.M.S. § 208.152(1)(3, 6, 8, 14, 18).

85. Medi-Cal is responsible in California for the administration of services provided in accordance with Title XIX, Public Law 89-97, 1965 amendments to the federal Social

Security Act, 42 U.S.C. § 301. Medi-Cal, https://www.dhcs.ca.gov/services/medi-cal/Pages/default.aspx (last visited July 19, 2019).

86. Medi-Cal provides coverage for outpatient prescription drugs and outpatient laboratory, x-ray services, and various other advanced imaging procedures based on medical necessity. *Id.*

87. CMS-1500 forms are used to submit claims for services to Medicaid in the same way they are used to submit claims to Medicare.

88. To gain payment under Medicaid for covered drugs, a manufacturer must enter a standardized agreement with HHS; in the agreement, the manufacturer undertakes to provide rebates to States on their Medicaid drug purchases. *Astra USA, Inc. v. Santa Clara County*, 563 U.S. 110, 131 (2011)(citing 42 U.S.C.A. § 1396r-8(a)). Once a drug manufacturer enters into a rebate agreement, the law requires the State to provide coverage for that drug under its plan unless the State complies with one of the exclusion or restriction provisions in the Medicaid Act. *Pharm. Research & Mfrs. Of Am. V. Walsh*, 538 U.S. 644, 652 (2003)(citing 42 U.S.C. § 1396r-8(d)).

89. Similar to Medicare, a Medicaid plan participant will receive reimbursements only for a covered outpatient drug, which is defined exactly the same way as for Medicare. *In re Plavix Marketing*, 123 F. Supp.3d at 607. A covered outpatient drug is a drug which may be dispensed only upon prescription. 42 U.S.C.A. § 1396r-8(k)(2)(A).

C. Prescription Drug Regulations

90. A prescription for a controlled substance must be dated and signed on the date when issued. The prescription must include the patient's full name and address, and the practitioner's full name, address, and DEA registration number. The prescription must also

include: (1) drug name; (2) strength; (3) dosage form; (4) quantity prescribed; (5) directions for use; and (6) number of refills (if any) authorized. U.S. Dep't of Justice, Drug Enforcement Administration, Practioner's Manual – Section V – Valid Prescription Requirements, https://www.deadiversion.usdoj.gov/pubs/manuals/pract/section5.htm (last visited July 18, 2019). A prescription for a controlled substance must be written in ink or indelible pencil or typewritten and must be manually *signed by the practitioner* on the date when issued. An individual (secretary or nurse) may be designated by the practitioner to prepare prescriptions for the *practitioner's signature* (emphasis added). *Id.*

91. A prescription for a controlled substance may be issued only by an individual practitioner who is: (1) authorized to prescribe controlled substances by the jurisdiction in which he is licensed to practice his profession and (2) either registered or exempted from registration pursuant to 21 C.F.R. §§ 1301.22(c) and 1301.23. 21 C.F.R. § 1306.03(a).

92. Every person who dispenses, or who proposes to dispense, any controlled substance, shall obtain from the Attorney General a registration issued in accordance with the rules and regulations promulgated by him. 21 U.S.C.A. § 822(a)(2).

93. Agents and employees may be exempt from registration under the following circumstances:

(a) The requirement of registration is waived for any agent or employee of a person who is registered to engage in any group of independent activities, if such agent or employee is acting in the usual course of his/her business or employment. 21 C.F.R. § 1301.22(a)

(b) An individual practitioner who is an agent or employee of another practitioner (other than a mid-level practitioner) registered to dispense controlled substances

may, when acting in the normal course of business or employment, administer or dispense (other than by issuance of prescription) controlled substances if and to the extent that such individual practitioner is authorized or permitted to do so by the jurisdiction in which he or she practices, under the registration of the employer or principal practitioner in lieu of being registered him/herself. 21 C.F.R. § 1301.22(b)

(c) An individual practitioner who is an agent or employee of a hospital or other institution may, when acting in the normal course of business or employment, administer, dispense, or prescribe controlled substances under the registration of the hospital or other institution which is registered in lieu of being registered him/herself, provided that:

(1) Such dispensing, administering or prescribing is done in the usual course of his/her professional practice;

(2) Such individual practitioner is authorized or permitted to do so by the jurisdiction in which he/she is practicing;

(3) The hospital or other institution by whom he/she is employed has verified that the individual practitioner is so permitted to dispense, administer, or prescribe drugs within the jurisdiction;

(4) Such individual practitioner is acting only within the scope of his/her employment in the hospital or institution;

(5) The hospital or other institution authorizes the individual practitioner to administer, dispense or prescribe under the hospital registration and designates a specific internal code number for each individual

practitioner so authorized. The code number shall consist of numbers, letters, or a combination thereof and shall be a suffix to the institution's DEA registration number, preceded by a hyphen (e.g., APO123456-10 or APO123456-A12); and

(6) A current list of internal codes and the corresponding individual practitioners is kept by the hospital or other institution and is made available at all times to other registrants and law enforcement agencies upon request for the purpose of verifying the authority of the prescribing individual practitioner.

21 C.F.R. § 1301.22(c)

94. It shall be unlawful for any person knowingly or intentionally to acquire or obtain possession of a controlled substance by misrepresentation, fraud, forgery, deception or subterfuge. 21 U.S.C.A. § 843(a)(3).

95. Opioids, such as those prescribed for pain by PPM and Dr. Modh, are dangerous and most are categorized as Schedule II drugs by the DEA, the classification for the most potent legal drugs and the ones that have the potential to do the most harm. *Koon v. Walden*, 539 S.W.3d 752, 756 (Mo. Ct. App. 2017).

96. In Missouri tort law, the standard of care requires doctors to conduct a risk assessment with the patient *before* prescribing opioids, in which they discuss the risks versus the benefits of giving opioids to the particular patient for the particular pain. *Id.* Once a patient is taking opioids, he or she should be monitored regularly, meaning regular contact to assess pain levels and functioning and to check for side effects and behaviors that would suggest the patient

is becoming addicted. *Id*. The risk assessments and the results of monitoring a patient should be documented in the medical records. *Id*.

COUNT I

Violation of False Claims Act § 3729 *et seq*.
Billing for Unprovided Ultrasound-Guided Injections and Upcoding 20610 to 20611

97. Relator re-alleges and incorporates the allegations of ¶¶ 1-96 as though fully set forth herein.

98. Relator observed that the ultrasound machines at PPM's office did not have power cords and therefore were not functional during the time of her employment from May 2013 to September 2018.

99. From May 2013 until September 2018, injections were performed without the use of ultrasound guidance but were fraudulently billed using CPT 76942 or 20611.

100. In 2015, there were 329 instances of billing and submission of claims to Government healthcare payors for ultrasound-guided injections that were actually performed without ultrasound machines by PPM's facility and employees.

101. One example of this occurred on January 27, 2015 (Ex. A, 4). Medicare was billed on behalf of Patient B for an ultrasound-guided injection at a cost of $200.00. Medicare paid $31.03 on February 12, 2015 and Medicaid paid $26.70 on March 5, 2015 for an ultrasound-guided injection that was performed by Defendants without the use of an ultrasound machine. (*Id*.) Medicare, through either a MAC or MAP, was again billed by Defendants for the same procedure on March 24, 2015 (*Id*., 5), April 21, 2015 (*Id*., 6), May 19, 2015 (*Id*.), June 16, 2015 (*Id*., 7), July 14, 2015 (*Id*. at 8), August 11, 2015 (*Id*., 9), October 6, 2015 (*Id*., 10), and November 3, 2015 (*Id*.) Medicare and Medicaid submitted payments to PPM for each of these

dates for ultrasound-guided injections that were performed without the use of an ultrasound machine. (*Id.*, 5-10).

102. Medicare paid $43.36 on February 18, 2016 and Medicaid paid $14.57 on March 4, 2016 for a false 76942 claim submitted by Defendants to the MO MAC, MAPs, and MO HealthNet on February 2, 2016 (*Id.*, 11). Medicare paid $46.12 on April 29, 2016 for a false 76942 claim submitted by Defendants to the MO MAC, MAPs, and MO HealthNet on April 12, 2016 (*Id.*, 14). Medicare paid $46.12 on May 12, 2016 and Medicaid paid $11.76 on June 3, 2016 for a false 76942 claim submitted by Defendants to the MO MAC, MAPs, and MO HealthNet on April 26, 2016 (*Id.*, 15). Medicare paid $46.12 on July 7, 2016 and Medicaid paid $11.76 on July 15, 2016 for a false 76942 claim submitted by Defendants to the MO MAC, MAPs, and MO HealthNet on June 21, 2016 (*Id.*, 16). Medicare paid $46.12 on August 19, 2016 and Medicaid paid $11.76 on September 16, 2016 for a false 76942 claim submitted by Defendants to the MO MAC, MAPs, and MO HealthNet on August 2, 2016 (*Id.*, 17). Medicare paid $46.12 on September 29, 2016 and Medicaid paid $11.76 on October 21, 2016 for a false 76942 claim submitted by Defendants to the MO MAC, MAPs, and MO HealthNet on September 13, 2016 (*Id.*, 18). Medicare paid $46.12 on December 21, 2016 and Medicaid paid $11.76 on January 6, 2017 for a false 76942 claim submitted by Defendants to the MO MAC, MAPs, and MO HealthNet on December 6, 2016 (*Id.*, 19).

103. Medicaid paid $11.98 on May 5, 2017 for a false 76942 claim submitted by Defendants to the MO MAC, MAPs, and MO HealthNet on March 30, 2017 (*Id.*, 21). Medicare paid $46.94 on July 24, 2017 and Medicaid paid $11.98 on August 16, 2017 for a false 76942 claim submitted by Defendants to the MO MAC, MAPs, and MO HealthNet on June 20, 2017 (*Id.*, 23-24). Medicare paid $46.94 on December 21, 2017 and Medicaid paid $11.98 on January

16, 2018 for a false 76942 claim submitted by Defendants to the MO MAC, MAPs, and MO HealthNet on December 5, 2017 (*Id.*, 26). Medicare paid $46.94 on January 1, 2018 for a false 76942 claim submitted by Defendants to either the MO MAC or a MAP on September 12, 2017 (*Id.*, 24).

104. Medicaid paid $11.96 on April 5, 2018 for a false 76942 claim submitted by Defendants to MO HealthNet on February 28, 2018 (*Id.*, 26). Medicaid paid $11.96 on April 17, 2018 for a false 76942 claim submitted by Defendants to MO HealthNet on January 31, 2018 (*Id.*, 26-27). A false 76942 claim was submitted to either the MO MAC, a MAP, or MO HealthNet on April 25, 2018 (*Id.*, 27). A false 76942 claim was submitted to either the MO MAC, a MAP, or MO HealthNet on May 23, 2018 (Id.) A false 76942 claim was submitted to either the MO MAC, a MAP, or MO HealthNet on June 20, 2018 (*Id.*, 28). Claims submitted in 2018 that Exhibit A does not show Government reimbursement for were likely reimbursed after Relator's departure. This is more likely than not based on the past patterns of Government reimbursement shown in Exhibit A.

105. Defendants upcoded services that should have been billed using 20610 by billing using 20611.

106. Medicare paid $69.98 on February 26, 2016 and Medicaid paid $17.85 on March 18, 2016 for a false 20611 claim submitted by Defendants to the MO MAC, MAPs, and MO HealthNet on February 10, 2016 (*Id.*, 12). Medicare paid $69.98 on March 11, 2016 and Medicaid paid $17.85 on March 25, 2016 for a false 20611 claim submitted by Defendants to the MO MAC, MAPs, and MO HealthNet on February 18, 2016 (*Id.*) Medicare paid $69.98 on March 18, 2016 and Medicaid paid $17.85 on March 25, 2016 for a false 20611 claim submitted on March 1, 2016 (*Id.*, 12-13). Medicare paid $69.98 on March 31, 2016 for a false 20611 claim

submitted by Defendants to either the MO MAC or a MAP on March 15, 2016 (*Id.*, 13). Medicare paid $69.98 on March 31, 2016 for a false 20611 claim submitted by Defendants to either the MO MAC or a MAP on March 8, 2016 (*Id.*) Medicare paid $69.98 on April 27, 2016 for a false 20611 claim submitted by Defendants to either the MO MAC or a MAP on February 25, 2016 (*Id.*)

107. CPT code 20611 was used at least seven times during the year 2017 (*Id.* 20-23). Medicaid paid $91.12 on February 22, 2017 for a false 20611 injection claim submitted by Defendants to MO HealthNet on January 3, 2017 (*Id.*, 20). Medicare paid $71.44 on February 21, 2017 and Medicaid paid $18.22 on March 24, 2017 for a false 20611 injection claim submitted by Defendants to the MO MAC, MAPs, and MO HealthNet on February 2, 2017 (*Id.*, 21). Medicare paid $71.44 on May 3, 2017 and Medicaid paid $18.22 for a false 20611 injection claim submitted by Defendants to the MO MAC, MAPs, and MO HealthNet on April 13, 2017 (*Id.*, 22). Medicare paid $71.44 on May 23, 2017 and Medicaid paid $18.22 on June 16, 2017 for a false 20611 injection claim submitted by Defendants to the MO MAC, MAPs, and MO HealthNet on April 24, 2017 (*Id.*) Medicare paid $71.44 on May 24, 2017 and Medicaid paid $18.22 on June 16, 2017 for a false 20611 injection claim submitted by Defendants to the MO MAC, MAPs, and MO HealthNet on May 8, 2017 (*Id.*)

108. The patients' medical records did not support a justification for billing of ultrasound-guided injections and there were no pictures of the ultrasounds or records of the ultrasounds in the patients' medical records despite Defendants' claims on CMS-1500 forms.

109. Defendants PPM, Dr. Modh, and Yeast acted knowingly, or in deliberate ignorance or reckless disregard for the truth or falsity of information regarding services provided,

in falsifying CMS-1500 claims forms by affixing the CPT code, 76942, for ultrasound-guided injections to claims forms for the period from May 2013 through September 2018.

110. Defendants acted knowingly, or in deliberate ignorance or reckless disregard for the truth or falsity of information regarding services provided, in falsifying CMS-1500 claims forms by affixing CPT code 20611 for ultrasound-guided injections of major joints or bursae to claims forms for the period from May 2013 until September 2018.

111. Defendants then submitted, or caused to be submitted, these fraudulent and factually false records to the MAC for Missouri, which submitted the factually false claims to Medicare. Defendants also submitted, or caused to be submitted, the factually false records to MO HealthNet.

112. Defendants submitted, or caused to be submitted, fraudulent and factually false records to MAP providers, which in turn submitted the factually false records to Medicare.

113. Defendants knew these records and statements on the CMS-1500 forms were false because they knew they did not use ultrasound machines to perform any of the injections provided during the time period from May 2013 to September 2018. Defendants knew that the ultrasound machines in the office were not in working order. Defendants also knew that they would be receive more money by billing unguided injection services as if they had been performed with the use of an ultrasound guide.

114. Medicare and Medicaid, unaware of the falsity of the claims and/or statements made or caused to be made by PPM, Dr. Modh, and Yeast, paid and may continue to pay reimbursements for ultrasound-guided injection services that were not provided.

115. As a result of Defendants' actions, the U.S. Government overpaid Defendants when they were not entitled to receive these payments.

116. As a result of Defendants' actions, the U.S. was severely damaged and will continue to be severely damaged.

COUNT II

Violation of False Claims Act § 3729 *et seq.*
Billing for Medically Unnecessary Injections

117. Relator re-alleges and incorporates the allegations of ¶¶ 1-116 as though fully set forth herein.

118. Relator was told during the period of her employment by Dr. Modh that "If patients, don't get injections, we don't write a script."

119. The scripts referred to by Dr. Modh were for prescription pain medications, such as opioids.

120. Injections were frequently given to many patients more than once every three to four months, as is recommended. See ¶ 59.

121. For example, Patient B was given an injection on September 18, 2014 (Ex. A, 1), October 2, 2014 (*Id.* 2), November 5, 2014 (*Id.* 3), and December 30, 2014 (*Id.* 4). Medicare paid $55.55 on October 8, 2014 and Medicaid paid $14.17 on October 16, 2014 for the September 18, 2014 injection (*Id.*, 1). Medicare paid $55.55 on October 21, 2014 and Medicaid paid $14.17 on November 5, 2014 for the October 2, 2014 injection (*Id.*, 2). Medicare paid $55.55 on November 24, 2014 and Medicaid paid $14.17 on December 19, 2014 for the November 5, 2014 injection (*Id.*, 3). Medicare paid $55.55 on January 16, 2015 and Medicaid paid $14.17 on February 5, 2015 for the December 30, 2014 injection (*Id.*, 4).

122. Medicare paid $31.03 on February 12, 2015 and Medicaid paid $26.70 on March 5, 2015 for an injection given to Patient B on January 27, 2015. (*Id.*, 4-5). Medicare paid $45.76 on April 13, 2015 and Medicaid paid $11.67 on May 5, 2015 for a March 24, 2015 injection (*Id.*,

5). Medicare paid $45.76 on May 7, 2015 and Medicaid paid $11.67 on May 18, 2015 for an April 21, 2015 injection (*Id.*, 6). Medicare paid $45.76 on July 2, 2015 and Medicaid paid $11.67 on July 17, 2015 for a May 19, 2015 injection. (*Id.*, 7). Medicare paid $45.76 on July 6, 2015 and Medicaid paid $11.67 on July 17, 2015 for a June 16, 2015 injection (*Id.*) Medicare paid $45.99 on July 29, 2015 and Medicaid paid $11.73 for a July 14, 2015 injection (*Id.*, 8). Medicare paid $45.99 on September 2, 2015 and Medicaid paid $11.73 on September 18, 2015 for an August 11, 2015 injection (*Id.*, 9). Medicare paid $45.99 on October 21, 2015 and Medicaid paid $11.73 on November 5, 2015 for an October 6, 2015 injection (*Id.*, 10). Medicare paid $45.99 on December 31, 2015 for a November 3, 2015 injection (*Id.*)

123. Patient B was given overly frequent injections during the year 2017. Medicare and Medicaid submitted payments to Defendants for each injection (*Id.*, 25-26).

124. Medicaid paid $91.12 on February 22, 2017 for a false 20611 injection claim submitted by Defendants to the MO MAC, MAPs, and MO HealthNet on January 3, 2017 (*Id.*, 20). Medicare paid $71.44 on February 21, 2017 and Medicaid paid $18.22 on March 24, 2017 for a false 20611 injection claim submitted by Defendants to the MO MAC, MAPs, and MO HealthNet on February 2, 2017 (*Id.*, 21). Medicare paid $71.44 on May 3, 2017 and Medicaid paid $18.22 for a false 20611 injection claim submitted by Defendants to the MO MAC, MAPs, and MO HealthNet on April 13, 2017 (*Id.*, 22). Medicare paid $71.44 on May 23, 2017 and Medicaid paid $18.22 on June 16, 2017 for a false 20611 injection claim submitted by Defendants to the MO MAC, MAPs, and MO HealthNet on April 24, 2017 (*Id.*) Medicare paid $71.44 on May 24, 2017 and Medicaid paid $18.22 on June 16, 2017 for a false 20611 injection claim submitted by Defendants to the MO MAC, MAPs, and MO HealthNet on May 8, 2017 (*Id.*)

125. Medicaid paid $11.98 on May 5, 2017 for a false 76942 claim submitted by Defendants to the MO MAC, MAPs, and MO HealthNet on March 30, 2017 (*Id.*, 21). Medicare paid $46.94 on July 24, 2017 and Medicaid paid $11.98 on August 16, 2017 for a false 76942 claim submitted by Defendants to the MO MAC, MAPs, and MO HealthNet on June 20, 2017 (*Id.*, 23-24). Medicare paid $46.94 on December 21, 2017 and Medicaid paid $11.98 on January 16, 2018 for a false 76942 claim submitted by Defendants to the MO MAC, MAPs, and MO HealthNet on December 5, 2017 (*Id.*, 26). Medicare paid $46.94 on January 1, 2018 for a false 76942 claim submitted by Defendants to either the MO MAC or a MAP on September 12, 2017 (*Id.*, 24).

126. A false 76942 claim was submitted to either the MO MAC, a MAP, or MO HealthNet on January 3, 2018 (*Id.*, 26). Medicaid paid $11.96 on April 5, 2018 for a false 76942 claim submitted by Defendants to MO HealthNet on February 28, 2018 (*Id.*) Medicaid paid $11.96 on April 17, 2018 for a false 76942 claim submitted by Defendants to MO HealthNet on January 31, 2018 (*Id.*, 26-27). A false 76942 claim was submitted to either the MO MAC, a MAP, or MO HealthNet on April 25, 2018 (*Id.*, 27). A false 76942 claim was submitted to either the MO MAC, a MAP, or MO HealthNet on May 23, 2018 (Id.) A false 76942 claim was submitted to either the MO MAC, a MAP, or MO HealthNet on June 20, 2018 (*Id.*, 28). Claims submitted in 2018 that Exhibit A does not show Government reimbursement for were likely reimbursed after Relator's departure. This is more likely than not based on the past patterns of Government reimbursement shown in Exhibit A.

127. As shown by the evidence in ¶¶ 120-126, a significant amount of the injections performed at PPM's facility from May 2013 until September 2018 were medically unnecessary, in violation of Medicare Part B regulations.

128. Defendants acted knowingly, or in deliberate ignorance or reckless disregard to the truth or falsity regarding medical necessity, in falsifying CMS-1500 claims forms for the period of Relator's employment from May 2013 until September 2018 by certifying that the injection services reported with the requisite CPT codes on the form were medically necessary and by signing these forms.

129. Defendants knew this certification of medical necessity was material because they were on notice of the requirement of medical necessity based on the CMS-1500 form's express statement requiring that services provided be medically necessary.

130. Defendants knew, or acted in deliberate ignorance or reckless disregard of Government regulations, that the Government would not reimburse them for injections that were not medically necessary.

131. Defendants then submitted, or caused to be submitted, these CMS-1500 forms with falsely certified statements of medical necessity to the MAC, MAPs, and to MO HealthNet.

132. Medicare and Medicaid, unaware of the falsity of the claims and/or statements made or caused to be made by PPM, Dr. Modh, and Yeast, paid and may continue to pay reimbursements for services that were not medically necessary.

133. As a result of Defendants' actions, the U.S. Government paid Defendants when they were not entitled to reimbursement.

134. As a result of Defendants' actions, the U.S. was severely damaged and will continue to be severely damaged.

COUNT III

Violation of False Claims Act § 3729 *et seq.*
Billing Using Doctor UPIN for Services Performed by Unsupervised Nurse Practitioner

135. Relator re-alleges and incorporates the allegations of ¶¶ 1-134 as though fully set forth herein.

136. Ashley Davis ("Davis") is a Nurse Practitioner ("NP") who performed pain management exam services for patients at Defendant PPM's facility from January 2018 until June 2019.

137. On multiple occasions between January 2018 and June 2019, Davis performed these services when Dr. Modh was not present in PPM's office suite and immediately available to furnish assistance. Davis performed unsupervised services at the same time that Defendant Yeast fraudulently signed prescriptions due to Dr. Modh's absence.

138. On these occasions, Davis's services were not performed "incident to" the service of a physician, as required by 42 C.F.R. § 410.26, because Davis was not under the direct supervision of Dr. Modh or any other physician, meaning Dr. Modh was not present in the office suite and was not immediately available to furnish assistance when Davis was providing services, as required by 42 C.F.R. § 410.32(b)(3)(ii).

139. Davis became aware of Defendants' fraudulent billing practices and resigned her employment from PPM's office. Davis contacted Relator on Facebook asking if she could speak with Relator and subsequently told Relator that Defendants' billing practices were the reason for her departure in a telephone conversation that took place on July 7, 2019.

140. Exhibit A has a column labeled "Prov" for "Provider" and Provider 1 is Dr. Modh. The number "1" is provided in every single transaction for 2018 in the record, even though many of these visits were done by Davis while she was unsupervised.

141. These services should have been billed using Davis's UPIN, since she provided the services without Dr. Modh's direct supervision, and Defendants should have subsequently been reimbursed by Medicare at 85 percent of the value of the service provided under the physician fee schedule as established by Medicare Part B regulations.

142. Defendants PPM, Dr. Modh and Jeannine Yeast acted knowingly, or in deliberate ignorance or reckless disregard for truth or falsity, in falsifying CMS-1500 claims forms for services provided by Davis from January 2018 until June 2019 by affixing Dr. Modh's UPIN on the CMS-1500 form.

143. Defendants were on notice of the requirements for claiming "incident to" services because of the statement on the back of the CMS-1500 form listing the requirements to certify that services were provided "incident to" the services of a physician.

144. Defendants knew, or deliberately ignored or recklessly disregarded the regulations involving nurse practitioner services, that billing using Dr. Modh's UPIN would result in a higher reimbursement than billing using Davis's UPIN.

145. Defendants then submitted, or caused to be submitted, these fraudulent and factually false records to the MAC for Missouri, which submitted the factually false claims to Medicare. Defendants also submitted, or caused to be submitted, the factually false records to MO HealthNet.

146. Medicare and Medicaid, unaware of the falsity of the claims and/or statements made, or caused to be made, by PPM, Dr. Modh, and Jeannine Yeast, paid and may continue to pay reimbursements for physician services that were actually rendered by an unsupervised NP.

147. As a result of Defendants' actions, Medicare reimbursed Defendants for these office visits for 100 percent of the value of the service provided under the physician fee schedule

when Defendants were only entitled to receive 85 percent of the value of the service provided under the physician fee schedule.

148. As a result of Defendants' actions, the U.S. was severely damaged and will continue to be severely damaged.

COUNT IV

Violation of False Claims Act § 3729 *et seq.*
Upcoding of Office Visits

149. Relator re-alleges and incorporates the allegations of ¶¶ 1-147 as though fully set forth herein.

150. Defendants billed Government payors for outpatient office visits using CPT code 99214 when they should have been billed using 99213 or 99212.

151. Relator was told by Defendant Jeannine Yeast that billing under 99214 was less suspicious than billing under 99215 and that billing at 99214 was being done to cover the costs for employing the NP, Ashley Davis, and to make more money.

152. Relator witnessed when patients entered PPM's facility and was responsible for writing the times when patients were checked out of the office as well as writing times for when the patients' vitals were taken.

153. Relator thus had firsthand knowledge of the exams that were performed and observed that patients received exams that were billable at 99212 and 99213, but not 99214.

154. Relator also witnessed patients being left in rooms for hours at a time, without being seen by Dr. Modh or NP Davis, so that Defendants could justify billing at a higher level.

155. Exhibit A shows that Patient B had a total of 40 exams coded under 99214 for treatment from September 2, 2014 to June 20, 2018. This averages out to about 10 upper level

exams per year. By comparison, Exhibit A shows that Patient B had just 13 exams coded under 99213 for the same time period.

156. For example, Patient B received an expanded office visit exam at 99214 on March 29, 2016 (Ex. A, 13), April 12, 2016 (*Id.*,14), and April 26, 2016 (*Id.*, 15). It is unlikely that Patient B needed a detailed history, detailed examination, and/or made medical decisions of moderate complexity 3 times in one month.

157. Medicaid paid $21.34 on February 22, 2017 for a false 99214 claim submitted by Defendants to MO HealthNet on January 17, 2017 (*Id.*, 21). Medicaid paid $21.34 on May 5, 2017 for a false 99214 claim submitted by Defendants to MO HealthNet on March 30, 2017 (*Id.*) Medicare paid $83.63 on May 3, 2017 and Medicaid paid $21.34 on May 16, 2017 for a false 99214 claim submitted by Defendants to the MO MAC or a MAP and MO HealthNet on April 13, 2017 (*Id.*, 21-22). Medicare paid $83.63 on July 24, 2017 and Medicaid paid $21.34 on August 16, 2017 for a false 99214 claim submitted by Defendants to the MO MAC or a MAP and MO HealthNet on June 20, 2017 (*Id.*, 23). Medicare paid $83.63 on September 1, 2017 and Medicaid paid $21.34 on September 15, 2017 for a false 99214 claim submitted by Defendants to the MO MAC or a MAP and MO HealthNet on August 15, 2017 (*Id.*, 24).

158. Medicaid paid $21.50 on April 5, 2018 for a false 99214 claim submitted by Defendants to MO HealthNet on February 28, 2018. (*Id.*, 26). Medicaid paid $21.50 on April 17, 2018 for a false 99214 claim submitted by Defendants to MO HealthNet on January 31, 2018 (*Id.*) Medicare paid $89.87 on April 17, 2018 for a false 99214 claim submitted by Defendants to either the MO MAC or a MAP on March 28, 2018 (*Id.*, 27).

159. Defendants PPM, Dr. Modh, and Jeannine Yeast acted knowingly, or in deliberate ignorance or reckless disregard to the truth or falsity of the information regarding the

examination services performed, in falsifying CMS-1500 claims forms by upcoding using CPT code 99214 when less comprehensive examinations were actually provided.

160. Defendants then submitted, or caused to be submitted by MAP providers, these factually false and fraudulent records to Medicare.

161. Defendants submitted, or caused to be submitted by MO's MAC, factually false and fraudulent records to Medicare.

162. Defendants submitted, or caused to be submitted, factually false and fraudulent records to MO HealthNet.

163. Medicare and Medicaid, unaware of the falsity of these claims, then reimbursed, and will continue to reimburse Defendants for a higher amount than the amount to which Defendants were/are truly entitled.

164. As a result of Defendant's actions, the U.S. was severely damaged and will continue to be severely damaged.

COUNT V

Violation of False Claims Act § 3729 *et seq.*
Forgery of Doctor's Signature On Narcotic Scripts

165. Relator re-alleges and incorporates the allegations of ¶¶ 1-163 as though fully set forth herein.

166. Defendant Jeannine Yeast forged Dr. Modh's signature on prescription slips for narcotics when the doctor was otherwise unavailable and Defendant Yeast then submitted these fraudulent script sheets to pharmacies and patients.

167. The prescriptions were signed by Defendant Jeannine Yeast and then Relator was instructed to write the other details of the prescription, including the name of the medication and the dose.

168. Relator witnessed Defendant Jeannine Yeast fraudulently signing the prescription slips by signing Dr. Modh's name.

169. Examples of blank scripts that were fraudulently signed using Dr. Modh's name by Defendant Jeannine Yeast are provided in Exhibit B.

170. Pharmacies and patients received these prescriptions with the fraudulent signatures and claims were then presented for these fraudulently signed prescriptions to offerors of MAPs that provided Medicare Part D drug coverage. Pharmacies and patients also presented claims for these prescriptions to Medicare PDP providers.

171. Defendants caused pharmacies and patients to submit claims for fraudulently signed opioid prescriptions to MAP offerors.

172. Defendants subsequently caused MAP providers to submit claims for fraudulently signed opioid prescriptions to Medicare, in violation of § 3729.

173. Signatures on the prescription slips indicate compliance with 21 C.F.R. §§ 1306.03(a), 1301.22, 1301.23, and 42 U.S.C.A. § 822.

174. Furthermore, there is no provision in any of the aforementioned statutes that allow for an employee who has not obtained the requisite registration with the DEA to commit forgery by signing a registered physician's name on a prescription slip. Other statutes regulating controlled substances expressly bar forgery. *See* 21 U.S.C.A. § 843(a)(3).

175. A signed prescription indicates that the physician has met the standard of care in assessing and evaluating patients' need and fitness for pain treatment using these dangerous drugs.

176. Therefore, a valid signature is material to Government reimbursement for these prescriptions. The Government regulates these drugs because it knows that these prescriptions

should only be given under certain circumstances while under the direction of an authorized physician and the Government knows the status of the ongoing public health crisis that is the opioid epidemic, for which multiple pharmaceutical manufacturers are undergoing litigation. It is unlikely the Government would knowingly reimburse prescriptions for opioids that were given without the requisite care of a physician and that were not subsequently filled out and signed by the physician.

177. Defendants knew, or acted in deliberate ignorance or reckless disregard for Government regulations of controlled substances, that a doctor's signature was material to the Government's decision to reimburse Defendants for prescriptions because Yeast forged Dr. Modh's signature, instead of using her own and attempting to claim she is exempt from registration under 21 C.F.R. § 1301.22. Defendants also knew that any claims submitted to Medicare Part D and Medicaid for prescription drug coverage were false because of Yeast's forgery of Dr. Modh's signature.

178. Medicare and Medicaid, unaware of the falsity of the claims and/or statements made or caused to be made by PPM, Dr. Modh, and Jeannine Yeast, paid and may continue to pay reimbursements for opioid prescriptions that were not authorized and signed by a qualified physician and, therefore, may unknowingly continue to contribute to the epidemic of opioid addiction.

179. As a result of Defendants' actions, the U.S. was severely damaged and will continue to be severely damaged.

COUNT VI

Violation of False Claims Act § 3729 *et seq.* and Federal Anti-Kickback Statute
Double Billing for Urine Tests and Compensation for Urine Samples

180. Relator re-alleges and incorporates the allegations of ¶¶ 1-178 as though fully set forth herein.

181. Defendant Yeast sent urine samples of patients from PPM to Defendant USL for testing that had already been completed in PPM's in-office laboratory.

182. Exhibit A, Page 21 shows a billing statement for a "commercial UDS," performed in the office by Jeannine Yeast, from January 17, 2017. The "balance" column shows that the value of this service is $105. The sample that was collected for this test was also sent out to USL, where the testing was repeated and then billed a second time to Government healthcare payors.

183. Medicare paid $70.39 on February 22, 2018 for a Commercial UDS claim that was performed by Yeast, but falsely billed using Dr. Modh's UPIN, and submitted by Defendants to either the MO MAC or a MAP on January 31, 2018 (Ex. A., 26). On March 28, 2018, a sample used in an in-office urine drug screen performed by Yeast for Patient B was sent to Defendant USL. PPM billed to Medicare at a cost of $105. (*Id.*, 27). On April 17, 2018, Medicare paid $70.39 for this service. (*Id.*) Defendant USL received the same urine samples that had already been tested and billed Government healthcare payors for the exact same services that had already been performed in PPM's in-office laboratory and reimbursed by Government payors.

184. Defendant USL compensated Defendant Yeast in exchange for these samples and to induce Yeast to send further shipments of urine samples from PPM patients, in violation of 42 U.S.C. § 1320a-7(b)(2).

185. USL billed Government healthcare payors for the same tests that were billed as "commercial UDS" by PPM, resulting in double billing and subsequent defrauding of the US Government. These tests were medically unnecessary as they had already been done by PPM.

186. USL acted knowingly, or in deliberate ignorance or reckless disregard for the truth or falsity of the information related to these urine tests, in falsifying CMS-1500 claims forms by certifying that the urine drug tests it performed were medically necessary, as is required for payment under Medicare Part B regulations. USL also falsely certified compliance with the Federal Anti-Kickback Statute, as is expressly stated as a requirement on the back of CMS-1500 claims forms.

187. USL also acted knowingly, or in deliberate ignorance or reckless disregard for the truth or falsity of the information related to urine tests, in falsifying CMS-1500 claims forms by affixing the CPT code for urine drug testing to the forms. These claims were false because they had already been billed to and reimbursed by Government healthcare payors after submission of these same claims by PPM, Yeast, and Dr. Modh.

188. USL then submitted, or caused to be submitted, to either or both the CA or MO MAC, MAP providers, and either or both Medi-Cal and/or MO HealthNet, these false and fraudulent claims.

189. USL then caused the CA or MO MAC and MAP providers to submit these false claims to Medicare.

190. Medicare and Medicaid, unaware of the falsity of the claims and/or statements made or caused to be made by Yeast and USL, reimbursed USL for urine drug screening services that had already been performed by Yeast in PPM's laboratory and for tests that resulted from the illicit compensation arrangement between Yeast and USL.

191. As a result of Defendants' actions, the U.S. Government has been severely harmed and will continue to be severely damaged.

COUNT VII

Violation of False Claims Act § 3729 *et seq.*
Medically Unnecessary Urine Tests and Testing Ordered by Nonphysician

192. Relator re-alleges and incorporates the allegations of ¶¶ 1-190 as though fully set forth herein.

193. Defendant Yeast ordered Urine Drug Screen tests for PPM patients when she was/is not a licensed physician nor an authorized nonphysician practitioner, as statutorily defined in 42 C.F.R. § 410.32(a)(2).

194. Relator witnessed Yeast order and perform in-office urine tests on numerous occasions.

195. For example, a urine test was ordered by Yeast and falsely billed using Dr. Modh's UPIN on August 15, 2017 and Medicare paid $77.25 on September 1, 2017 for this service (Ex. A, 24).

196. A urine test was ordered by Yeast and falsely billed using Dr. Modh's UPIN on March 28, 2018 and Medicare paid $70.39 on April 17, 2018 for this service (*Id.*, 27).

197. Tests not ordered by the physician or nonphysician practitioner who is treating the beneficiary are not reasonable and necessary. 42 C.F.R. § 410.32(a).

198. Compliance with 42 C.F.R. § 410.32(a) is material because the Government would not reimburse these urine drug screens if the Government healthcare agencies had known that an unlicensed office manager with no medical training who was privy to a compensation arrangement that constituted a kickback was ordering these urine tests.

199. Defendant USL also knew, or acted in deliberate ignorance or reckless disregard for the truth or falsity of Yeast's qualifications, that Defendant Yeast was not a licensed healthcare professional and that she was therefore violating 42 C.F.R § 410.32(a) in ordering urine tests and by inducing her to send samples for these orders to USL's facility.

200. Defendants knew that compliance with 42 C.F.R. § 410.32(a) was material because Defendants affixed Dr. Modh's UPIN on CMS-1500 claims forms for the tests. Defendants knew that using identifying information for Yeast, who has no healthcare license, would result in the claims being rejected.

201. Defendants also knew that one of the main purposes for ordering and performing these urine tests was to be compensated illicitly by USL in exchange for urine testing services covered by federal healthcare programs, in violation of 42 U.S.C. § 1320a-7(b)(2).

202. Defendants, therefore, acted knowingly, or in deliberate ignorance or reckless disregard of the truth or falsity of the information regarding medical necessity, in falsifying CMS-1500 claims forms by certifying that these urine drug screen tests were medically necessary, in violation of 42 C.F.R. § 410.32(a), and by affixing Dr. Modh's UPIN to the forms, in violation of § 3729 *et seq*.

203. Defendants then submitted these falsified CMS-1500 forms to MACs, MAPs, Medi-Cal, and MO HealthNet.

204. Medicare and Medicaid, unaware of the falsity of the claims and/or statements made or caused to be made by Defendants, reimbursed Defendants for urine tests that were not medically necessary and were not ordered by a physician.

205. As a result of Defendants' actions, the U.S. Government has been severely harmed and will continue to be severely damaged.

PRAYER FOR RELIEF

WHEREFORE, Relator respectfully asks this Court to enter judgement against PPM, Dr. Nehal P. Modh, M.D., Jeannine Yeast, and USL in the following:

(a) That PPM, Dr. Nehal P. Modh, M.D., Jeannine Yeast, and USL be ordered to cease and desist from submitting and/or causing to be submitted any more false claims or otherwise violating 31 U.S.C. §§ 3729 *et seq.*;

(b) That civil penalties be imposed of not less than Five Thousand ($5,000.00) Dollars nor more than Ten Thousand ($10,000.00) Dollars for each and every false claim presented to the United States, multiplied as provided by 31 U.S.C. §§ 3729 *et seq.*;

(c) That Relator be awarded the maximum amount allowed pursuant to 31 U.S.C. § 3730(d);

(d) That judgment be entered for Relator and against PPM, Dr. Nehal P. Modh M.D., Jeannine Yeast, and USL for any costs, including, but not limited to, court costs, expert fees, and all attorneys' fees, costs, and expenses for which Relator necessarily incurred in bringing this case;

(e) That pre- and post-judgment interests be awarded;

(f) That the Court grant permanent injunctive relief to prevent any recurrence of the False Claims Act violations for which redress is sought in this complaint;

(g) That civil penalties of $100,000 be imposed on Defendants for each false record submitted to Government healthcare payors pursuant to 42 U.S.C.A. § 1320(a)(8);

(h) For such other and further relief as the Court deems just and proper under the circumstances.

JURY TRIAL DEMANDED

Relator, on behalf of herself and the United States of America, demands a jury trial on all claims alleged herein.

Dated: July 26, 2019

Respectfully Submitted,

THE SIMON LAW FIRM, P.C.

By: */s/ Anthony G. Simon*

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VERIFICATION

I declare under penalty of perjury that the foregoing is true and correct. Executed on 7-22, 2019.

Donna Chronister

DONNA CHRONISTER